



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 150382KB		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/CZ2004/000053		International filing date (day/month/year) 31.08.2004	Priority date (day/month/year) 02.09.2003	
International Patent Classification (IPC) or national classification and IPC A61K9/19, A61K47/00				
Applicant PLIVA-LACHEMA A.S. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 30.03.2005		Date of completion of this report 10.08.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Kardas-Llorens, E Telephone No. +49 89 2399- 		

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-5 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
- 3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
- 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-5
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-5
Industrial applicability (IA)	Yes: Claims	1-5
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

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Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial
 applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 94/12193 A (DEBIOPHARM S.A; IBRAHIM, HOUSSAM; IRIE, TERUKO; MAUVERNAY, ROLLAND-YVE) 9 June 1994 (1994-06-09)
- D2: MATHÉ G ET AL: "Oxalato-platinum or 1-OHP, a third-generation platinum complex: an experimental and clinical appraisal and preliminary comparison with cis-platinum and carboplatinum" BIOMEDICINE AND PHARMACOTHERAPY, ELSEVIER, PARIS, FR, vol. 43, 1989, pages 237-250, XP002094674 ISSN: 0753-3322
- D3: DE 103 14 377 A1 (STADA ARZNEIMITTEL AG) 7 October 2004 (2004-10-07)

Novelty:

The present application does meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-5 is new in the sense of Article 33(2) PCT.

None of the cited prior art documents discloses a composition comprising the specific weight ratio as claimed in claim 1.

Inventive step:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-5 does not involve an inventive step in the sense of Article 33(3) PCT.

The present problem to be solved is the provision of an oxaliplatin lyophilizate which is stable and which has an alcoholic sugar of non-animal origin as a carrier.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and 4, and discloses a composition of oxaliplatin lyophilizate in combination with an alcoholic sugar of non-animal origin such as a carrier (see in particular claim 7, examples and p. 4, 3rd § in D1).

The subject-matter of claim 1 therefore differs from this known oxaliplatin lyophilizate in that the weight ratio of oxaliplatin to the alcoholic sugar of non-animal origin is 1:3 to 1:7. However, the selected weight ratio does not seem to contribute to establish inventive step over D1, since no evidence over the importance of the selected weight

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ratio for the stabilizing characteristics of the composition is derivable from the present application. Thus, the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 4, which therefore is also considered not inventive.

Re Item VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
DE-A-10314377	07.10.04	28.03.03	